

REMARKS

The Office Action dated September 3, 2009 has been carefully reviewed and the following comments are made in response thereto. In view of the following remarks, Applicants respectfully request reconsideration and reexamination of this application and the timely allowance of the pending claims.

Claims 1-117 are pending in this application. Claims 21-34, 27-117 are withdrawn from consideration. Without prejudice or disclaimer and for the sole purpose of advancing prosecution, Applicants have cancelled claims 1, 3, 6-12, 14, 16, 20, 25 and 26. Applicants have amended claim 2 to recite a method of quantitating a known biological molecule and claim 15 to recite that the biological molecule is selected from the group consisting of a protein, a lipid, a sugar chain, and a nucleic acid. In addition, as a result of claim cancellations, Applicants have also amended certain claims to change the dependency. Exemplary support for these amendments can be found on page 11, line 19 to page 12, line 17, page 62, line 21 to page 63, line 12 and Examples 5 to 7 (page 110 line 18 to page 108, line 13) of the specification. No new matter is added.

Double Patenting

The Office Action objected to claim 24, alleging that this claims is a substantial duplicate of claims 1, 2 or 6 (see page 2 of the Office Action). Since Applicants have canceled claim 25, this objection is moot.

The Rejection under 35 U.S.C. § 112, first paragraph should be withdrawn.

Claims 1-20, 25 and 26 were rejected under 35 U.S.C. § 112 for allegedly lacking enablement. Applicants respectfully disagree for the reasons that follow.

Prior to discussing this rejection in detail, Applicants note that claims 1, 3, 6-12, 14, 16, 20, 25 and 26 were canceled without prejudice or disclaimer and for the sole purpose of advancing prosecution. Accordingly, the rejection of these claims is moot.

The Office Action alleges that the specification is enabling for the method for which the biological molecule is known (*see* page 2 of the Office Action). As amended, pending claims are directed to methods of quantitating known biological molecules and accordingly the claims are enabled.

The Rejections under 35 U.S.C. § 112, second paragraph should be withdrawn.

Claims 1-20 and 25-26 were rejected under 35 U.S.C. § 112, second paragraph for allegedly being indefinite.

Prior to discussing these rejections in detail, Applicants note that claims 1, 3, 6-12, 14, 16, 20, 25 and 26 were canceled without prejudice or disclaimer and for the sole purpose of advancing prosecution. Accordingly, the rejection of these claims is moot.

Claims 1, 3-4, 6-7 and 9-11 were rejected as being allegedly incomplete for allegedly omitting essential steps, the omission of which was alleged to amount to a gap between the steps. Specifically, these claims were alleged to omit the step of obtaining metabolically isotope labeled biological molecules. Applicants have amended the pending claims to recite such a step and accordingly this rejection is moot.

Furthermore, in order to clarify claim 15, Applicants have amended this claim to recite that the biological molecule is selected from the group consisting of a protein, a lipid, a sugar chain, and a nucleic acid. Applicants submit that claim 15, as amended, is definite.

In light of the foregoing amendments and remarks, Applicants request withdrawal of the rejections under 35 U.S.C. § 112, second paragraph.

The Rejection under 35 U.S.C. § 101 should be withdrawn.

Claims 25 and 26 were rejected for allegedly being improper process claims under 35 U.S.C. § 101 (*see* page 4 of the Office Action). Since claims 25 and 26 have been canceled, this rejection is moot.

The Rejections under 35 U.S.C. § 102(a) and 103(b) should be withdrawn.

Claims 1-10 and 13-19 were rejected under 35 U.S.C. § 102(a) for allegedly being anticipated by Wu *et al.* Claim 20 was rejected under 35 U.S.C. § 103(a) for allegedly being obvious over Wu *et al.*

As the Examiner is aware this application is a U.S. National Stage Application of PCT/JP2004/017370, which claims the benefit of two Japanese applications. The Wu *et al.* article published after the filing of the two Japanese applications but before the filing of the PCT application. Applicants respectfully submit that the pending claims are clearly supported by the disclosure of these two Japanese applications and are thus entitled to their priority date. Accordingly, Wu *et al.* is not available as prior art and the rejections under 35 U.S.C. §§ 102(a) and 103(b) should be withdrawn.

In addition, Applicants respectfully submit that even if Wu *et al.* were prior art, the reference cannot anticipate or render the pending claims obvious. The pending claims are directed to the quantitation of known biological molecules that cannot be labeled metabolically with great good accuracy. Wu *et al.* fails to disclose or suggest all of the elements of the pending claims. In particular, Wu *et al.* fails to disclose or suggest (1) obtaining a cell containing an internal standard substance by culturing a cell derived from the same species and tissue as the sample in culture medium comprising an isotope labeled precursor of the biological sample, (2) adding the obtained cell to the sample and (3) performing a mass spectrometric analysis.

In light of the foregoing amendments and remarks, Applicants respectfully request withdrawal of the rejections under 35 U.S.C. §§ 102(a) and 103(a).

Conclusion

It is respectfully submitted that all claims are now in condition for allowance, early notice of which would be appreciated. Should the Examiner disagree, Applicants respectfully request a telephonic or in-person interview with the undersigned attorney to discuss any remaining issues and to expedite the eventual allowance of the claims.

Except for issues payable under 37 C.F.R. 1.18, the Commissioner is hereby authorized by this paper to charge any additional fees during the entire pendency of this application including fees due under 37 C.F.R. 1.16 and 1.17 which may be required, including any required extension of time fees, or credit any overpayment to Deposit Account 50-0310.

Respectfully submitted,

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